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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,242	11/07/2008	Ruben Martin Lageuns	0003048USU/2442	9613
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OHLANDT, GREELEY, RUGGIERO & PERLE, LLP ONE LANDMARK SQUARE, 10TH FLOOR STAMFORD, CT 06901			EXAMINER KASSA, JESSICA M	
			ART UNIT 1616	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/585,242

Applicant(s)

MARTIN LAGEUNS ET AL.

Examiner

JESSICA KASSA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

**Claims 1 and 3-22 are pending and are under consideration in the instant office action.**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-5 provides for the use of idebenone, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### **Response to Arguments**

Applicants argue that claim 1 has been amended to require a method step. This is not found persuasive since the claim clearly recites “use” and has not been amended to recite “A method of...”

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 3-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### **Response to Arguments**

Applicants argue that claim 1 has been amended to require a method step. This is not found persuasive since the claim clearly recites “use” and has not been amended to recite “A method of....”

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 6-8, 10-15, and 18-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Neudecker et al. (WO 01/03657; US 6756045 B1 English language equivalent).**

Neudecker et al. teach cosmetic and topical dermatological preparations containing an effective amount of idebenone and/or its derivatives (column 1, lines 11-13). The cosmetic and dermatological preparations contain anti-oxidants in combination with idebenone and/or its derivatives (column 1, lines 25-27). With respect to instant claims 6-8, the amount of idebenone is 0.5% in example 8 (column 15). A cream, a gel, an emulsion and a spray (i.e. aerosol) are found on examples 1-3 and 7-12. With respect to instant claim 14, the idebenone is in a liposome containing gel in example 7. With respect to instant claim 18, example 8 contains butylmethoxy dibenzolymethane

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and alpha-tocopherol. With respect to instant claim 19, example 7 contains alpha-tocopherol.

In particular, cosmetic preparations provide effective protection from damaging oxidation processes in the skin. Active ingredient combinations and preparations serve for the prophylaxis and treatment of light-sensitive skin, in particular photodermatoses. The method includes skin change from damage to the skin by ultraviolet light (claim 4). Therefore, Neudecker et al teach a method of treating unwanted skin pigmentation comprising applying an effective amount of idebenone.

Ester oils such as isopropyl myristate are advantageously used (column 8, line 45). Saturated and/or unsaturated, branched and/or unbranched alcohols of chain length 3-30C may be used; the examiner notes that this would include cetyl alcohol. Waxes such as cetyl palmitate may be used (column 9 lines 1-3). Examples 1 and 3-5 contain vaseline, petrolatum, and/or beeswax. The compositions may contain glycerine (column 8, line 27, column 9, line 36). The compositions may contain preservatives and paraben (example 3).

### **Response to arguments**

Applicants argue that Neudecker discloses the use of idebenone as an antioxidant and free-radical scavenger and to prevent skin changes induced by aging, wrinkling, exposure to ultraviolet degenerative process and oxidation of skin. Applicants further argue that in the present invention, idebenone has a direct inhibitory effect on the enzyme tyrosinase catalyzing the conversion of tyrosine into melanin which is unrelated to the antioxidant effects. Applicants further argue that idebenone produces

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lightening of normal, non-UV exposed human skin, or skin affected by cloasma, etc. and that the mechanism of action disclosed in the instant application is not anticipated or even suggested by Neuducker. This is not found persuasive since the mode of action and the particular types of conditions treated are irrelevant for the composition claims and are not even recited in method claims 20-21. Moreover, the instant application clearly also teaches photodamaged skin as a skin disorder to be treated which is clearly one of the conditions Neudecker et al. teaches (claim 4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 6, 14, and 16-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker et al. (WO 01/03657; US 6756045 B1 English language equivalent) as applied to claims 6-8, 10-15, 18-20 above, and further in view of Holocomb (US 5607667).**

***Applicants' claims***

Applicants claim a cosmetic, pharmaceutical and/or dermatological composition comprising idebenone or a derivative thereof

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

The reference of Neudecker et al. is discussed in detail above and that discussion is hereby incorporated by reference.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***

***(MPEP 2141.02)***

Neudecker does not explicitly teach propylparaben and methylparaben. This deficiency is cured by Holocomb.

Holocomb teaches a body care composition containing the following body care components 58.39% water, 12.81% isopropyl myristate, 8.44% mineral oil, 4.00% glycerine, 3.84% sorbitan stearate, 2.00% cocoa butter, 1.43% beeswax, 1.20% stearic acid, 1.20% cetyl alcohol, 1.12% polysorbate 60, 1.00% aloe vera oil, 0.99% glyceryl stearate S.E., 1.00% dimethicone, 0.75% triethanolamine, 0.30% sodium borate, 0.25% panthanol, 0.15% fragrance, 0.15% propylparaben, 0.15% methylparaben, 0.83% of an

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aqueous suspension of 500 ppm colloidal silica, and 0.25% sodium hydroxymethyl glycinate.

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time the present invention was made to incorporate propylparaben and methylparaben and thus produce the instantly claimed invention since Neudecker et al. already teach the incorporate of paraben and other preservatives. A person of ordinary skill in the art would have been motivated to include the propylparaben and methylparaben in order to preserve the composition. A person of ordinary skill in the art would have had a reasonable expectation of success since Neudecker already teach the incorporation of paraben.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

**Response to Arguments**

Applicants argue that the rejection over Neudecker et al. in view of Holcomb is overcome for the reasons set forth above. Applicants' arguments are addressed above and that discussion is incorporated herein by reference.

**Claims 6 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker et al. (WO 01/03657; US 6756045 B1 English language equivalent) as applied to claims 6-8, 10-15, and 18-20 above, and further in view of Houze et al. (US 2004/0018241 A1).**

***Applicants' claims***

Applicants claim a cosmetic, pharmaceutical and/or dermatological composition comprising idebenone or a derivative thereof.

***Determination of the Scope and Content of the Prior Art***  
***(MPEP 2141.01)***

The reference of Neudecker et al. is discussed in detail above and that discussion is hereby incorporated by reference.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***  
***(MPEP 2141.02)***

Neudecker et al. do not explicitly teach a patch. This deficiency is cured by Houze et al.

Houze et al. teach a bioadhesive compositions in a flexible, finite form for topical application to the skin (abstract and paragraph 77). The examiner notes that this constitutes an occlusive patch. Suitable active include idebenone (paragraph 340).

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time the present invention was made to incorporate the idebenone in a patch and thus produce

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the instantly claimed invention since Houze et al. teach idebenone in a occlusive patch.

A person of ordinary skill in the art would have been motivated to incorporate the idebenone in a patch in order to administer idebenone topically. A person of ordinary skill in the art would have had a reasonable expectation of success since Houze et al. teach the incorporation of idebenone in a patch.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

### **Response to Arguments**

Applicants argue that the rejection over Neudecker et al. in view of Houze is overcome for the reasons set forth above. Applicants' arguments are addressed above and that discussion is incorporated herein by reference.

**Claims 20-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker et al. (WO 01/03657; US 6756045 B1 English language equivalent) as applied to claims 6-8, 10-15, and 18-20 above, and further in view of Jensen et al. (US 2002/0192245 A1).**

### ***Applicants' claims***

Applicants claim a cosmetic, pharmaceutical and/or dermatological composition comprising idebenone or a derivative thereof.

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

The reference of Neudecker et al. is discussed in detail above and that discussion is hereby incorporated by reference.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***

***(MPEP 2141.02)***

Neudecker et al. do not explicitly teach allowing the composition to act overnight or rinsing off the composition in the morning. This deficiency is cured by Jensen et al. (US 2002/0192245 A1).

Jensen et al. teach a night cream moisturizer comprising tocopherol acetate (example 1). The rejuvenating ointment or cream is applied for nocturnal or resting treatment.

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time the present invention was made to apply the idebenone containing composition overnight and rinse it off in the morning and thus produce the instantly claimed invention since Jensen et al. teach the rejuvenating ointment or cream for nocturnal or resting treatment. A person of ordinary skill in the art would have been motivated to apply the idebenone containing composition overnight and rinse it off in the morning to moisturize, heal, and sooth the vulnerable and delicate surface of the skin. A person of ordinary skill in the art at the time the present invention was made would have had a reasonable

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expectation of success since the compositions of Neudecker et al. and Jensen et al. are both cosmetic compositions comprising antioxidants such as tocopherol.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

### **Response to Arguments**

Applicants argue that the rejection over Neudecker et al. in view of Jensen et al. is overcome for the reasons set forth above. Applicants' arguments are addressed above and that discussion is incorporated herein by reference.

### **Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA KASSA whose telephone number is (571)270-1342. The examiner can normally be reached on 5:30am- 2pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica M. Kassa  
Patent Examiner  
AU 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616